CLAIMS

1. A method for detecting an analyte in a fluid sample comprising:

(a) mixing said fluid sample with a reagent comprising a capturing agent which is a first member of a binding couple that can bind to an analyte, the analyte being a second member of the binding couple, such that if the analyte is present in the fluid sample, particulates of the binding couple are formed;

(b) treating said mixture so as to form on a solid substrate a thin layer of said particulates, if formed as a result of said mixing;

(c) obtaining an optical image of the thin layer; and

(d) analyzing said optical image so as to determine therefrom the absence or presence of particulates formed as a result of the association between the binding couple, the presence of particulates in the sample indicating the presence of said analyte in the sample; or to determine from said image at least one parameter of said particulates.

2. The method of Claim 1, wherein said analyte comprises at least two recognitions sites and said capturing agent comprises at least two capturing moieties, such that particulates of binding couples are formed by association of a recognition site of said analyte with a capturing moiety of said capturing agent.

3. The method of Claim 1 or 2, wherein said parameter is selected from: particulate size; size distribution of the particulates; particulates' count; shape of the particulates; or spatial distribution of the particulates.

4. The method of any one of Claims 1 to 3, wherein said image is a magnified image of said the thin layer of said mixture.

5. The method of Claim 4, wherein said magnification is achieved by the use of a light microscope lens.

6. The method of any one of Claims 1 to 5, wherein said analyte is a particle comprising on its surface two or more copies of a recognition site with which a

capturing agent can associate, thereby forming particulates of said binding couple.

7. The method of Claim 6, wherein said particle is a cell or a microorganism presenting on their surface said recognition sites.

8. The method of Claim 7, wherein the recognition site is an antigen and said capturing agent is an antibody having affinity to said antigen.

9. The method of any one of Claims 1 to 5, wherein said reagent comprises microbeads having a sensing interface, the sensing interface carrying two or more copies of a capturing moiety such that if said analyte is present in the fluid sample, particulates of binding couples are formed by association of said capturing moieties on said microbead with recognition sites of said analyte;

10. The method of Claim 9, wherein said sensing interface carries two or more copies of a same capturing moiety.

11. The method of Claim 9, wherein said sensing interface carries two or more copies of different capturing moieties.

12. The method of any one of Claims 10 to 12, wherein said microbeads are affinity microbeads.

13. The method of Claim 13, wherein said microbeads are immunobeads.

14. The method of any one of the preceding claims, wherein said thin layer comprises a monolayer of particulates of said binding couple.

15. A system for performing the method of any one of Claims 1 to 14, the system comprising:

(a) holding means for holding a solid substrate carrying a thin layer of particulates;

(b) an optical image acquisition device for capturing an image of the thin layer on the solid substrate;

(c) an image analysis device coupled to said image acquisition device and for analyzing an image obtained by the image acquisition device.

16. The system of Claim 15, further comprising a magnifying device.

17. The system of Claim 16, wherein said magnifying device comprises a light microscope lens.

18. The system of Claim 17, wherein said magnifying device is a light microscope.

19. The system of any one of Claims 15 to 18, wherein said optical image acquisition device is a camera.

20. The system of any one of Claims 15 to 19, wherein said image acquisition device is coupled to a magnifying device.

21. The system of to any one of Claims 15 to 20, wherein the image analysis comprises determination of one or more a parameter of particulates formed within the thin layer, the parameter selected from size of particulates, size distribution of particulates, particulates' count; particulates' shape and spatial distribution of the formed particulates.

22. A kit for use in the method of any one of Claims 1 to 15, the kit comprising:

(a) at least one reagent comprising a capturing agent being a first member of a binding couple and comprising at least two capturing moieties to which binds an analyte, if present in a tested fluid sample, the analyte being a second member of the binding couple,

(b) a solid substrate for carrying a thin layer of particulates.

23. The kit of Claim 22, wherein said solid substrate is a microscope slide or a testing chamber.

24. The kit of Claim 22 or 23, wherein said solid support is adapted for use in combination with an optical image acquisition device.

25. The kit of any one of Claims 22 to 24, comprising means for creating said thin layer.